Remarks

Claims 15-23 and 26 are pending in the present application. Claims 15-23 and 26 have been finally rejected by the Examiner.

By the above amendments, Claims 15-17 and 19-20 have been canceled, and Claims 18, 21 and 26 amended to more particularly point out and distinctly claim the subject matter which Applicants regard as the invention. More specifically, Claim 26 has been amended to incorporate the limitations formerly found in Claims 16, 17 and 20, and claims 18 and 21 amended to change the dependencey. Applicants submit that the amendments are fully supported by the application as originally filed, and no new matter is being added. After entry of the amendments, Claims 18, 21-23 and 26 will remain pending and under consideration.

The Examiner has rejected Claims 15-23 and 26 under 35 U.S.C. §103(a) as allegedly unpatentable over the combination of PDR (page 2058 of the 52d edition) and U.S. Patent Nos. 5,260,072 ('072), 5,133,974 ('974), and 5,084,278 ('278). Applicants respectfully traverse the rejection.

The PDR teaches topiramate as a drug with a bitter taste which is useful as an antiepileptic drug.

The '072 patent teaches rotagranulation and taste masking coatings for preparing chewable pharmaceutical tablets containing bitter tasting drugs (e.g., famotidine). The '072 patent does not teach sugar spheres and teaches that the rotagranules are preferably 150 to 400 microns (0.150-0.400 mm) which is well outside the size range limitation of amended claim 1 which requires an initial particle size between about

0.710 mm and 1.18 mm and a final particle size between about 0.850 mm and 1.18 mm. (*See, e.g.*, col. 3, lines 58-59 of '072)

The '974 patent teaches extended release formulations comprising a core comprising immediate release particles having the drug, sugar spheres, and binder where the immediate release particles are coated with a dissolution modifying agent. The '974 patent discloses a size range of "-10+60 U.S. Standard mesh size" for the immediate release particles which is a very large range, but provides no other guidance as to the size of the particles. By way of example, 18 mesh is 1 mm and 60 mesh is 0.250 mm, so a range of 18 to 60 mesh would be from 0.250 mm to 1 mm. The '974 patent does not provide any teaching or suggestion which would motivate one of ordinary skill in the art to make and administer a formulation with a particle having an initial particle size between about 0.710 mm and 1.18 mm and a final particle size between about 0.850 mm and 1.18 mm as is required by amended Claim 26.

The '278 patent teaches taste masked microcapsule formulations which can be sprinkled onto foods and that can provide immediate release of active agents in the stomach. The '278 patent does not teach sugar spheres and discloses a preferred uncoated acetaminophen particle size range of 150 to 300 micrometers (0.150 mm to 0.300 mm) and claims a microcapsule of about 10 microns (0.010 mm) to about 1.5 mm in diameter (see col. 10, lines 66-68 and claims 1 and 9). The '278 patent provides no teaching or suggestion which would motivate one of ordinary skill in the art to make and administer a formulation as claimed in amended claim 26 which requires an initial particle size between about 0.710 mm and 1.18 mm and a final particle size between about 0.850 mm and 1.18 mm as is required by amended Claim 26.

Applicants submit that the combined teachings of the PDR, '072, '974 and '278 do not render the present invention obvious. The combined teachings would not motivate one of ordinary skill in the art to make and use the claimed invention which requires a pharmaceutical composition comprising core particles containing an active agent of topiramate, a binder and sugar spheres wherein the core particles have an initial particle size between about 0.710 mm and 1.18 mm; and a taste mask coating, wherein the taste mask coating comprises between about 9% by weight and about 13% by weight of the pharmaceutical composition and wherein the coated particles of the pharmaceutical composition have a final particle size between about 0.850 mm and 1.18 mm.

Further, Applicants submit that the formulations taught by the '072 patent and the '974 patent would not be suitable for sprinkling onto soft food and swallowing, as is required in the presently claimed invention. The '072 patent teaches a chewable taste-masked tablet formulation which cannot be sprinkled and swallowed. The '974 patent teaches a controlled release capsule which is intended to be swallowed intact in order to provide the desired release profile.

Additionally, Applicants submit that the pharmaceutical compositions of the claimed invention result in a product which was unexpectedly found to have a superior stability profile over prior art tablet formulations of topiramate. Applicants unexpectedly found that the coating used to taste mask the topiramate core beads also provides a barrier to the absorption of moisture, and therefore, improves on the stability of the sprinkle formulation. Although it was necessary to put a desiccant into the bottles to stabilize the

topiramate tablet formulation for storage, the sprinkle formulation does not require a desiccant. There is no need for a desiccant in spite of the fact that the capsules which are used to encapsulate the appropriate dosage of sprinkles contain more than 10% moisture by weight; it appears that this moisture does not accelerate the degradation of topiramate because of the taste mask coating for the sprinkles. (see page 17, lines 7-16 of the specification). This was a surprising and unexpected finding by Applicants, which was in no way suggested by the prior art, either alone or in combination.

Applicants maintain that the claimed methods of the present invention are not obvious over the PDR, and US Patent Nos. 5,260,072, 5,133,974 and 5,084,278, either alone or in combination, and Applicants therefore respectfully request that the Examiner withdraw the rejection of claims 15-23 and 26 under §103(a).

In view of the above remarks, Applicants maintain that the application is in condition for allowance and passage to issue is earnestly requested.

Respectfully submitted,

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